Material Transfer Agreement
For Transfers of Division Biospecimen Resources to Approved Institutions

This Material Transfer Agreement (the "Agreement") is by and between the Division *of* Intramural Population Health Research (the "Division") of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, part of the National Institutes of Health, a component of the United States Department of Health and Human Services and *<insert name of institution>* ("Recipient") regarding the transfer of human biospecimens from the Division Repository (currently, held under contract by Fisher BioServices, 14665 Rothgeb Drive, Rockville, MD 20850 (Contractor)) to approved institutions for research purposes as further defined below. Throughout this Agreement, the Division and Recipient are collectively referred to as the "Parties." This Agreement will become effective upon the date of the last signature affixed below.

The Division and Recipient agree as follows:

1. DEFINITIONS. Within this Agreement, the following terms will have the same meaning and effect as those set forth in the U.S. Code of Federal Regulations (CFR) 45 CFR Part 46 Protection of Human Subjects. Complete copies of this part can be accessed through: http://www.gpoaccess.gov/cfr/index.html. Also referenced in this MTA is OHSR Sheet 14 entitled "NIH Requirements for the Research Use of Stored Human Specimens and Data" which can be accessed at http://ohsr.od.nih.gov/info/sheet14.html.

(a) "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or
(2) Identifiable private information (IPI).

(b) "Unlinked" means materials that were initially collected with identifiers but, before research use, have been irreversibly stripped of all identifiers by use of an arbitrary or random alphanumeric code and the key to the code is destroyed, thus making it impossible for anyone to link the samples to the sources. This does not preclude linkage with existing clinical, pathological, and demographic information so long as all subject identifiers are removed prior to distribution or receipt.

(c) "Coded" means materials that are unidentified for research purposes by use of a random or arbitrary alphanumeric code but that may still be linked to their sources through use of a key to the code available to the Division.

(d) "Identified" means materials that are still attached to a readily available subject identifier such as name, social security number, study number, hospital number, medical record number, address, telephone number, etc., such that the identities of the subjects can be ascertained

2. DESCRIPTION OF MATERIAL AND DATA. The Division will transfer to the Recipient the following human biospecimens and/or derivatives thereof ("MATERIAL"):

<insert description of specific samples to be transferred>

The MATERIAL will be transferred with the following data ("DATA"):

<insert description of specific data to be transferred>.

3. TRANSFER OF MATERIAL AND DATA. The MATERIAL and DATA provided by Division will be unlinked and blinded. That is, biospecimens will be assigned a random identification number by the Division Repository, and the Repository will hold the key linking the DATA to the original identifiers (study identification number). All IPI will be removed. The MATERIAL will be relinked to existing resource datasets (unblinded) by the Division Repository after all approved laboratory analyses have been completed.

4. RESPONSIBILITIES AND AUTHORIZATIONS OF RECIPIENT.

(a) Recipient agrees to use the MATERIAL and DATA *for the approved research project only* (see Appendix 1 "Research Project").

Research Project: *<insert name of research project>*

(b) Recipient is responsible for obtaining or has obtained, and provided documentation of any necessary Institutional Review Board (IRB) research approvals or exemptions required to use the MATERIAL and DATA at the respective institution (see Appendix 2 "IRB Letter of Approval"). The MATERIAL and DATA will be used by the Recipient in compliance with all applicable Federal, state, and local statutes and regulations.

(c) Recipient will allow the use of MATERIAL and DATA only by *<insert name of Recipient P.I.>* ("Recipient Investigator") and Recipient Investigator's research team that are under the direct supervision of Recipient Investigator, and only after they have been informed of and agreed to the provisions and restrictions stated herein. Any transfer of MATERIAL and DATA to other than Recipient Investigator's research team requires the advanced written approval of the Division.

(d) It is acknowledged that the Recipient may already have in its possession or will obtain from another source, IPI related to the MATERIAL and DATA, and to which the Recipient may be subject to additional restrictions or obligations under separate agreements. Recipient shall notify the responsible IRB(s) and the Division in writing within five (5) working days of its discovery of any unauthorized use or disclosure of IPI related to the MATERIAL and DATA of which Recipient, its officers, employees, or agents become aware. Recipient shall take (i) prompt corrective action to cure any deficiencies or (ii) any action pertaining to such unauthorized disclosure required by applicable federal law.

(e) Recipient agrees not to identify or contact any donor, or living relative of a donor, who may have provided the MATERIAL or any DATA received by Recipient under this Agreement from Division unless the donor, or living relative of the donor, has given prior consent for contact as part of an ongoing research project approved by the Division.

(f) Recipient agrees to report data, inventions, and publications resulting from the use of the MATERIAL and/or DATA to Division and to submit to the Division a Recipient Investigator-certified dataset with all laboratory results linked to the resource database.

(g) Division retains ownership of the Materials and any functional subunits thereof contained or incorporated in derivatives. Inventions and ownership of intellectual property resulting from the research will be determined by U.S. patent law.

(h) There is no restriction on development of commercial products resulting from the knowledge gained from research using the Materials. Materials or material isolated from them, such as RNA, DNA, or protein, may not themselves be transferred to third parties for scientific or commercial purposes, or sold or distributed as commercial products. Division disclaims any knowledge relating to third-party property interest in the Materials.

5. THE MATERIAL AND DATA ARE NOT FOR USE IN HUMAN SUBJECTS OR FOR THE TREATMENT OR DIAGNOSIS OF HUMAN SUBJECTS.

6. DISCLAIMER. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE DIVISION MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE HUMAN MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. To the extent allowed by law, Recipient assumes liability for claims for damages against it by third parties which may arise from its use, storage, processing, distribution, or disposal of the MATERIAL except that, to the extent permitted by law, the Division shall be liable to Recipient when the damage is caused by the gross negligence or willful misconduct of the Division. This Agreement shall be construed in accordance with United States Federal law as applied by the Federal courts in the District of Columbia.

7. TERMINATION AND DISPOSAL. Violation of any element of this Agreement or significant deviation from the research protocol as approved is sufficient cause for **e**ither Party to terminate this Agreement with sixty (60) days written notice to the other Party. When the Research Project is completed or this Agreement is terminated, whichever comes first, any unused MATERIAL and DATA will either be destroyed in compliance with all applicable statutes and regulations or will be returned to the Division as requested by the Division.

8. ACKNOWLEDGEMENT. In all oral presentations or written publications resulting from the use of the MATERIAL and DATA, the Recipient will acknowledge the *<insert name of biospecimen resource>* as the source of the MATERIAL and DATA, unless requested otherwise by Division, as follows: "Biospecimens {and/or Derivatives} and associated data were provided by the*<insert name of biospecimen resource>*, an initiative developed through intramural funding from the *<insert funding source, if applicable>*."

9. COSTS AND SHIPPING. The MATERIAL and DATA are provided at the cost to Recipient of labor and materials for sample preparation, documentation, and shipping. The Division will notify Recipient when the MATERIAL and DATA are ready for shipment and will expect payment *at that time* for the negotiated costs involved in preparation of the resources for shipping and shipping costs (see Appendix 3 "Negotiated Cost Schedule"). Recipient will be responsible for the pick-up and shipment, including express shipping costs, of the MATERIAL and DATA.

Signatures begin on the next page.

The Parties have executed this Agreement by their respective duly authorized officers on the day and year hereinafter written. Any communication or notice to be given shall be forwarded in writing to the respective addresses listed below.

Research Project: *<insert name of research project>*

Signatures for Division:

_____ _____
Signature of Authorized Official **Date**

_____
Printed name & title of Director or Deputy Director NICHD

_____ _____
Signature of Authorized Official **Date**

_____
Printed name of Division Authorized Official

Certification of the Division Authorized Official: This Agreement __has / __has not been modified. If modified, the modifications are attached.

Signatures for Recipient
Recipient Scientist:
Recipient Organization:
Address:

_____ _____
Signature of Authorized Official **Date**

_____
Printed name and title of Authorized Official

Certification of Recipient Scientist: I have read and understood the conditions outlined in this Agreement and I agree to abide by them in the receipt and use of the MATERIAL and DATA.

_____ _____
Scientist Receiving Material **Date**